This Program Announcement expires on August 12, 2002, unless reissued.

BIOENGINEERING RESEARCH PARTNERSHIPS

Release Date: October 11, 2001

PA NUMBER: PAR-02-010

National Cancer Institute

National Eye Institute

National Heart, Lung, and Blood Institute

National Human Genome Research Institute

National Institute on Aging

National Institute of Allergy and Infectious Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute of Biomedical Imaging and Bioengineering

National Institute of Child Health and Human Development

National Institute on Drug Abuse

National Institute on Deafness and Other Communication Disorders

National Institute of Dental and Craniofacial Research

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of Environmental Health Sciences

National Institute of General Medical Sciences

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

National Institute of Nursing Research

National Library of Medicine

Notice of Intent Receipt Dates: December 21, 2001 and July 12, 2002 Application Receipt Dates: January 24, 2002 and August 12, 2002

PURPOSE

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) invite applications for R01 awards to support Bioengineering Research

Partnerships (BRPs) for basic and applied multi-disciplinary research that addresses important biological or medical research problems. A BRP is a multi-disciplinary research team applying an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. The partnership must include appropriate bioengineering or allied quantitative sciences in combination with biomedical and/or clinical investigators. A BRP may propose hypothesis-driven, discovery-driven, developmental, or design-directed research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities or combinations of these entities.

On October 1, 2001, NIH issued a related program announcement (PA) PA-02-011 for Bioengineering Research Grants (BRGs). The BRGs differ from the BRPs in that the BRG research will be performed in a single laboratory or by a small number of investigators.

BACKGROUND

Many of today's biomedical problems are best addressed using a multi-disciplinary approach that extends beyond the traditional biological and clinical sciences. Bioengineering integrates principles from a diversity of technical and biomedical fields and crosses the boundaries of many scientific disciplines represented throughout academia, laboratories, and industry. The creativity of interdisciplinary teams is resulting in new basic understandings, novel products, and innovative technologies for addressing biomedical problems.

Recognizing the importance of bioengineering in public health, the Bioengineering Consortium (BECON) was established in 1997 as a focus for bioengineering activities at the NIH. To facilitate communication between the allied and biomedical disciplines and to provide input from the scientific community on research needs and directions, the BECON has held annual two-day symposia on emerging topics of interest related to bioengineering including bioengineering (1998), bioimaging, (1999), nanotechnology (2000), and reparative medicine (2001). Summaries of the proceedings and recommendations of these symposia are available on the Internet at http://www.becon.nih.gov/becon_symposia.htm.

Discussions and recommendations of symposia participants aided the formulation of the BRP and BRG program announcements. Both the BRP and BRG PAs recognize that applications for bioengineering projects often focus on technology development rather than on proving or disproving scientific hypotheses. Therefore, the NIH review criteria for bioengineering applications submitted in response to these PAs have been modified to ensure that these proposals are evaluated appropriately and fairly.

In December 2000, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) was established at the NIH with a mission to improve health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities. In support of this mission, the NIBIB funds research aimed at developing fundamental or crosscutting technologies that can be translated into several biomedical applications. Studies involving technological application to a specific disease, organ system, or social issue will be considered by the appropriate NIH institute or center.

PROGRAM OBJECTIVES

One objective of this program announcement is to encourage basic and applied bioengineering research that could make a significant contribution to improving human health. Bioengineering integrates physical, engineering, and computational science principles for the study of biology, medicine, behavior, or health. It advances fundamental concepts, creates knowledge from the molecular to the organ systems level, and develops innovative biologicals, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

A second objective is to encourage collaborations and partnerships among the allied quantitative and biomedical sciences. A BRP should bring together necessary physical, engineering, or computational science expertise with biological or clinical resources to address a significant area of bioengineering research within the mission of the NIH. In addition to the benefits to be derived from the research, the collaborations and partnerships can create opportunities for transdisciplinary communication and training for a new generation of scientists capable of interacting across traditional technical boundaries.

RESEARCH OBJECTIVES

Applications for a BRP award should focus on an area of basic, applied, behavioral, or clinical research in bioengineering that supports the missions of the NIH institutes and centers and where progress is likely to make a significant contribution to improving human health.

MECHANISM OF SUPPORT

The mechanism of support will be the NIH R01 research grant. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total

requested project period for a competitively-reviewed application may not exceed five years. Detailed budgets are required for BRP applications.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit, non-profit, public, and private organizations. Examples of eligible organizations include universities, colleges, hospitals, national laboratories, industrial research organizations, large or small businesses, units of state and local governments, eligible agencies of the Federal government, and faith-based organizations. Foreign institutions are not eligible to apply. However, BRP collaborative projects may include work at a foreign site when the expertise at the foreign site is not present in the United States. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

FUNDS AVAILABLE

For any grant, the maximum total (direct plus indirect) costs to be awarded in any year is \$2 million. The number of awards and level of support will depend on the number of applications of high scientific merit that are received and the availability of funds. Funding in subsequent years will be contingent upon satisfactory progress during the preceding year(s) and the availability of funds. Applicants are encouraged to discuss budget requests with NIH scientific and financial contacts listed under INQUIRIES prior to submission. The initial period of support for a BRP award may be up to five years. The award may be competitively renewed for a second period up to five years. NIH does not envision more than one renewal period.

LETTER OF INTENT

Prospective applicants are asked to submit a one-page notice of intent by the deadlines given on the first page of this announcement. The letter of intent should consist of the number and title of the PA; a descriptive title of the proposed research; the name, address, telephone number, and e-mail address of the Principal Investigator; and the identities of other key personnel and participating institutions. The letter of intent is to be sent via email to noi@nibib.nih.gov.

BRP ORGANIZATIONAL STRUCTURE, LEADERSHIP, AND MANAGEMENT

An organizational structure that clearly defines the partnership and justifies relationships among the various components must be developed and described in the application. The BRP size, structure, and mode of operation should match the needs and scope of the proposed research.

The BRP Principal Investigator (PI) is responsible for management, staffing, and resource allocation and for administering the award in accordance with NIH policies. The PI has the responsibility and authority to use BRP funds in the most productive way to achieve the goals defined at the time of the award. To accomplish this task, the PI can adjust funding among BRP participants to support new partners or to reduce support to old partners as needed.

BRP PI MEETING

BRP PIs will meet annually to share results, to ensure that the NIH has a coherent view of the advances in these fields, and to have an opportunity for collective problem solving among the PIs. The cost of participating in this annual meeting should be included in the BRP budget.

APPLICATION PREPARATION INSTRUCTIONS

Applicants are strongly advised to contact IC scientific program staff listed under INQUIRIES to discuss the relevance of their proposed work to the institute's mission before preparing a detailed research application. Detailed information on research missions and programs for each NIH institute and center is available on the individual IC's Web sites which can be accessed through the NIH Homepage at http://www.nih.gov.

The PHS 398 research grant application instructions and forms (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html are to be used in applying for these grants and will be accepted at the standard application deadlines (http://grants.nih.gov/grants/dates.htm) as indicated in the application kit. This version of the PHS 398 is available in an interactive, searchable PDF format. Although applicants are encouraged to begin using the 5/2001 revision of the PHS 398 as soon as possible, the NIH will continue to accept applications prepared using the 4/1998 revision until January 9, 2002. Beginning January 10, 2002, however, the NIH will return applications that are not submitted on the 5/2001 version. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

The title and number of this program announcement must be typed on line 2 of the face page of the application form, and the YES box must be marked. Follow the PHS 398 instructions for "Preparing Your Application" with the following modifications and additions:

- 1. Page limitations have been increased to a maximum of 40 pages from the usual 25 page limit for sections A-D of the "Research Plan" of an application. This 40 page limit is an absolute maximum. Applicants are encouraged to be concise and use fewer pages.
- 2. Description Page The institution leading the BRP and any other participating institutions must be identified. The description should provide a clear indication of the area of bioengineering research that will be the focus of the BRP, the planned multidisciplinary approach, the specific milestones to be achieved, and timelines for achievement for the first year and additional years of the grant.
- 3. An organization chart (OC) that clearly defines the partnership and relationships among its various components must be included with the application. A program plan (PP) should accompany the OC and list major tasks with a timeline of expected milestones for the entire project period. The OC and PP must not exceed one page each. This information should be included in the Research, Design, and Methods section of the application.
- 4. BRP Budget Items A separate budget for each partner at a subcontract/consortium institution, and when appropriate for clarity, for each partner within the grantee institution must be included. Include a summary budget for all BRP participants with partners at non-grantee institutions shown as consortium arrangements.

The NIH ICs will not provide annual support in excess of \$2 million total cost for any year. Direct cost inflationary increases following the first year may be included, but the total cost maximum request level of \$2,000,000 per year must be observed.

The PI is expected to devote a minimum of 25% effort to the BRP. The percent effort requested for other personnel should be limited to time devoted specifically to BRP Partner activities and not to other research activities. Information documenting the level of effort on BRP activities should be included in the application. The need for all requested personnel costs should be thoroughly justified. The percent effort of the BRP PI should be justified in the context of the PI's other responsibilities. Administrative support (a secretary or an administrative assistant) may be requested for the BRP office only for matters directly pertaining to the BRP.

There will be an annual BRP PI meeting at a date and location to be determined by NIH staff.

Applicants should include travel funds specifically for these meetings in the BRP budget request.

Applicants may request and justify other travel funds in addition to the funds required for the annual PI meeting. Travel funds could be used to promote collaboration among BRP partners at different institutions or at a distant site, be used for travel of external advisors to the BRP site, and/or be used for BRP partners to attend scientific meetings essential to the progress of the BRP and for which other funds are not available.

Other expenses can be requested including costs necessary for the central administration and fiscal management of the BRP including relevant and reasonable costs for reprints, graphics, and publications.

With regard to projected funding by source, some BRP applicants may anticipate or receive commitments for significant funding from other than NIH sources; e.g., from a collaborating company. In this case, applications should describe the source, annual amount, and use of the other funding.

- 5. Other Support Provide a complete listing of current and pending support for the Principal Investigator, Co-Investigator(s), and other key personnel for grantee and partnering organizations.
- 6. Resources The application should describe the equipment and facilities available for the proposed BRP.

If the BRP entails an institutional commitment of resources across boundaries in the institution or anticipates the provision of institutional resources, include letters from appropriate senior-level individuals describing their agreements to support those commitments.

Where appropriate, describe the shared facilities to be established including specific major research instruments and plans for the development of instruments. Describe plans for maintaining and operating the facilities including staffing, provisions for user fees, and plans for ensuring access to outside users. Distinguish between existing facilities and those still to be developed.

7. Research Plan

A. Specific Aims – Applications submitted in response to this program announcement may be design-, problem, need-, or hypothesis-driven. Thus, the application should state the hypotheses, designs, problems, and/or needs that will drive the proposed research. Describe the specific aims in the appropriate area of bioengineering research and the goals for the first year and for the long term. Describe the expected applications of the bioengineering research that will improve human health. One page is recommended.

- B. Background and Significance Briefly describe the area of bioengineering research that is the focus of the BRP. Critically evaluate existing knowledge and approaches that have been or are being applied in the area and specifically describe how the proposed BRP approach will advance the field. State concisely the importance and health relevance of the research proposed to achieve the Specific Aims.
- C. Preliminary Studies and Rationale Preliminary studies that support the proposed research should be described in the application.
- D. Research Design and Methods A BRP should focus on a systems approach in a significant area of bioengineering research. Describe an overall research plan that is sufficiently long term (five to ten years) to justify organizing a BRP and adaptable enough to permit change as the research proceeds. Clearly indicate current activities, why a BRP is necessary, and what unique opportunities will be provided by the proposed BRP. Explain the integrative-engineering approach and why such an approach is essential to the proposed research. If the proposed BRP research is closely related to ongoing research or an existing center, explain how the research activities of the BRP will complement but not overlap existing research. Describe the contributions of each partner and how these will be integrated and organized to accomplish the specific aims of the project. Provide a tentative sequence or timetable for the project. If appropriate to the project, state quantitative milestones corresponding to timetable events. Include a description of how the data will be collected, analyzed, and interpreted. Discuss major technical challenges and possible alternative approaches to achieve the aims. Describe plans for enhancing the abilities and opportunities for investigators and trainees to work across disciplinary boundaries.

Applications should include a plan for making available to the research community any technologies developed or enhanced by work conducted as part of the program announcement. This plan should be described in the Research Design and Methods section of the application. Investigators using PHS funds are required to make unique research resources readily available for research purposes to qualified individuals within the scientific community when the results

have been published. The intent of this policy is not to discourage, impede, or prohibit the organization the develops the unique research resources or intellectual property from commercializing the products.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES.

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary for the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

APPENDICES

Applicants are advised that the 40-page application should contain all relevant information. Appendix materials should not be submitted with the application. Reviewers are not obligated to read appended materials. Applicants who wish to send appendices should wait until they receive notification that the application has been assigned to an Initial Review Group. At that time, they should contact the Scientific Review Administrator of the committee to which their application is assigned to receive further instructions.

APPLICATIONS EXCEEDING \$500,000 PER YEAR DIRECT COSTS

In accordance with NIH policy (http://grants.nih.gov/grants/guide/notice-files/not98-030.html), an applicant planning to submit a proposal that requests \$500,000 or more in direct costs for any year must obtain approval to submit the application from scientific program staff at a research institute or center. This approval must be obtained at least six weeks before the application deadlines (December 13, 2001, and July 1, 2002, for this program announcement). The applicant must identify the institute or center and the scientific program staff member who agreed to accept assignment of the application in the cover letter that transmits the proposal.

A list of scientific program contacts for each of the NIH IC's is available on the Internet at http://www.becon.nih.gov/becon_contacts.htm. Applications exceeding \$500,000 per year direct costs in any year that are submitted without this approval will be returned.

APPLICATION SUBMISSION INSTRUCTIONS

Submit a signed, typewritten original of the application, including the Checklist, and five signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW

NATIONAL INSTITUTES OF HEALTH

6701 ROCKLEDGE DRIVE

ROOM 1040 - MSC 7710

BETHESDA, MD 20892-7710

BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the application deadline dates given on the first page of this solicitation. If an application is received after that date, it will be returned to the applicant without review.

REVISED APPLICATIONS

The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantive revision of an application already reviewed, but such an application must include an introduction addressing the previous critique.

REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by CSR staff. Applications that are complete will be evaluated for scientific and technical merit by Scientific Review Groups of the CSR. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit (generally the top half of applications under review) may be discussed, assigned a priority score, and receive a second-level review by the appropriate national advisory council or board.

REVIEW CRITERIA

The NIH review criteria have been adapted to ensure that the BRP application is evaluated appropriately. The score should reflect the overall impact that the BRP award could have on the selected area of bioengineering research based on consideration of the five criteria given below.

The emphasis on each criterion can vary from one application to another depending on the nature of the application and its relative strengths. An application need not be strong in all categories to be judged likely to have major technical or scientific impact and thus deserve a high priority score. For example, an investigative partnership may propose to perform important work that by its nature is not innovative but is essential to advance a field.

A BRP may propose discovery-driven, developmental, non-hypothesis-driven, design-directed, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities. The review criteria include:

- 1. Significance. If the specific aims of the BRP are achieved, will they provide significant advances in the selected area of bioengineering research? Is the research likely to have a significant impact on other areas of research? Will the technological advances have a significant impact on human health?
- 2. Approach. Are the BRP engineering, scientific and clinical approaches and methods adequately developed, well integrated, and appropriate to the aims of the project? Does the application address potential problem areas and consider alternative strategies? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing technological progress?

Is the proposed partnership adequate for the research? Is the partnership strategy well-planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the technology developed (including through commercialization)? Is the plan for sharing or disseminating technologies developed or enhanced under this program announcement adequate? Do they describe arrangements that facilitate the fruitful participation of a partner at a distant site? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

- 3. Innovation. Does the BRP propose new approaches, explore new research paradigms, or represent new concepts that combine engineering, physical, and clinical sciences? Will the proposed approaches or concepts solve current scientific or technical problems in novel ways?
- 4. Investigators. Is the PI capable of coordinating and managing the proposed BRP? Are the investigators (partners) appropriately trained in their disciplines and capable of conducting the proposed interdisciplinary work?

5. Environment. Does the scientific and technological environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements within the partnership? Is there evidence of institutional support? Does the partnership create potential opportunities to foster transdisciplinary communication and training across traditional scientific and technical boundaries?

AWARD CRITERIA

BRP applications will compete for available funds with all other recommended applications. Funding decisions will be based on the quality of the proposed research as determined by peer review, availability of funds, and the institute's programmatic priority for the focus of the proposed research.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" published in the "NIH Guide for Grants and Contracts" on August 2, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html).

Recent revisions relate to NIH-defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available on the Internet at http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is available in the NIH Guide for Grants an Contracts, June 5, 2000 (Revised August 25, 2000), available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease

prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority

areas. This program announcement is related to one or more of the priority areas. Potential

applicants may obtain a copy of "Healthy People 2010" on the Internet at

http://www.health.gov/healthypeople/.

INQUIRIES

Inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions

from potential applicants is welcome.

Inquiries or contacts concerning institute-specific scientific or financial issues should be directed

to the NIH BECON scientific or financial contacts listed at the following Web site:

http://www.becon.nih.gov/becon_contacts.htm.

These scientific contacts can also be used to obtain permission to submit applications that

request more the \$500,000 of direct costs in any year.

Inquiries regarding general programmatic issues should be directed to:

Dr. Richard E. Swaja

National Institute of Biomedical Imaging and Bioengineering

31 Center Drive – Room 1B37

Bethesda, MD 20892-2077

TEL: 301-451-6771

FAX: 301-480-4515

E-mail: swajar@nibib.nih.gov

Inquiries concerning review issues should be directed to:

Dr. Eileen Bradley

Center for Scientific Review

6701 Rockledge Drive

Bethesda, MD 20892

TEL: 301-435-1179

FAX: 301-480-2241

E-mail: bradleye@csr.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.394, 93.395, 93.396, 93.306, 93.867, 93.172, 93.837, 93.838, 93.839, 93.866, 93.273, 93.855, 93.856, 93.846, 93.864, 93.865, 93.929, 93.279, 93.173, 93.121, 93.847, 93.848, 93.849, 93.113, 93.821, 93.859, 93.862, 93.242, 93.853, 93.361, and 93.879. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The NIH Grants Policy Statement is available at

http://grants.nih.gov/grants/policy/policy.htm. This document includes general information about the grant application and review process; information on the terms and conditions that apply to NIH grants and cooperative agreements; and a listing of pertinent offices and officials at the NIH.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or, in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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